NOVARTIS

FEMARA®

(letrozole)

2.5 mg Film-coated tablets

Basic Succinct Statement

CODE: BSS RD 15 DEC 2016; APPR 16 OCT 2017
This material is only meant for Healthcare Professionals

FEMARA®

Important note: Before prescribing, please consult full prescribing information.

Presentation: letrozole. Film-coated tablet containing 2.5 mg active substance for oral use.

Indications: ▪ Adjuvant treatment of postmenopausal women with hormone receptor positive early breast cancer. ▪ Adjuvant treatment of postmenopausal women with early breast cancer (positive or unknown oestrogen or progesterone receptor status) who have received 5 years of adjuvant tamoxifen therapy (extended adjuvant therapy). ▪ First-line treatment in postmenopausal women with hormone-dependent advanced breast cancer. ▪ Treatment of advanced breast cancer in women with natural or artificially induced postmenopausal status, who have previously been treated with antioestrogens. ▪ Pre-operative therapy in postmenopausal women with localised hormone receptor positive breast cancer, to allow subsequent breast-conserving surgery in women not originally considered candidates for this type of surgery. Subsequent treatment after surgery should be in accordance with standard of care.

Dosage: 2.5 mg once daily.

Contraindications: Hypersensitivity to letrozole or excipients. Premenopausal endocrine status; pregnancy, breast-feeding.

Warnings/Precautions: ♦Careful consideration of risk/benefit in patients with creatinine clearance <10 mL/min. ♦Patients with severe hepatic impairment (Child-Pugh score C) should be kept under close supervision. ♦Consider adequate contraception in women who have the potential to become pregnant, including women who are perimenopausal or who recently became postmenopausal, until postmenopausal status is fully established. (LH, FSH, and/or estradiol levels measurement recommended). ♦Monitoring of bone health. ♦Avoid co-administration with tamoxifen, other anti-estrogens or estrogen-containing therapies. ♦Caution when driving and using machines

Pregnancy, lactation, females and males of reproductive potential

Pregnancy: ♦Femara may cause fetal harm when administered to a pregnant woman. The patient should be apprised of the potential risk to the fetus, if Femara is used during pregnancy or if the patient becomes pregnant while taking this drug.

Lactation: ♦It is not known if letrozole is excreted in human milk. A nursing woman should be advised on the potential risks to the child. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for Femara and any potential adverse effects on the breast-fed child from Femara or from the underlying maternal condition.

Females and males of reproductive potential: ♦*Contraception:* Sexually active females of reproductive potential should use effective contraception.

Infertility: Based on animal studies, Femara may impair fertility in males of reproductive potential.

Adverse reactions: ♦***Most common adverse reactions***: hot flushes, nausea, fatigue, (including asthenia and malaise), increased sweating, hypercholesterolemia, arthralgia.

♦***Common adverse reactions are***: anorexia, appetite increase, peripheral edema, headache, dizziness, vomiting, dyspepsia, constipation, diarrhea, alopecia, rash, myalgia, bone pain, back pain, fall, arthritis, osteoporosis, bone fractures, weight increase, depression, vaginal bleeding, dry skin, hypertension, palpitations, vertigo, chest pain, abdominal pain.
♦***Uncommon, rare or very rare, or frequency not known adverse reactions and potentially serious***: leukopenia, cataract, cerebrovascular accident or infarction, thrombophlebitis, pulmonary embolism, arterial thrombosis, general edema, ischemic cardiovascular disease, angioedema, anaphylactic reaction, hepatitis, toxic epidermal necrolysis, erythema multiforme, carpal tunnel syndrome, trigger finger, hyperbilirubinemia and jaundice.